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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/037,677	10/23/2001	Volker Schellenberger	GC560-D1	1582

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GENENCOR INTERNATIONAL, INC.
ATTENTION: LEGAL DEPARTMENT
925 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1636

13

DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/037,677

Applicant(s)

SCHELLENBERGER ET AL.

Examiner

Maria B Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 13 January 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 49-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 49, 53 and 55 is/are rejected.
- 7) ☒ Claim(s) 50-52, 54 and 56-58 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This Office action is in response to the amendment filed 4/10/03, Paper No. 12. Claims 49-58 are pending in this application.

Response to Amendment

Receipt of a substitute Paper Copy of the Sequence listing, a substitute Computer Readable Form of the Sequence Listing and a letter stating that no new matter has been added is acknowledged. Objections to the Specification due to sequence disclosures that were not identified by SEQ ID Nos. and that were not contained in the Sequence listing are withdrawn in light of submission of corresponding SEQ ID NOs.

Rejection of claim 53 under 35 U.S.C. 112, second paragraph, is withdrawn in light of amendment to claim 53. Specifically, applicant has amended the claims to remove reference to wild-type genes *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS*, *mutU*.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 49 and 55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 6,365,410. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims are anticipated by and would have been obvious over the reference claim. **This rejection is maintained for reasons of record in Paper No. 11, mailed 1/13/03 and repeated below.**

Both the claim in the 6,365,410 patent and the instant claims 49 and 55 recite a method for preparing an evolved microorganism said microorganism containing a heterologous protein. The claims differ in that claim 3 in the 6,365,410 patent reads on a heterologous protein that is selected from the group consisting of hormones, enzymes and growth factors while the instantly claimed invention recites a heterologous protein that is an enzyme (claim 49) or any enzyme necessary for an enzymatic pathway (claim 55) and includes within the claim that the microorganism to be cultured is also obtained. Claim 49 and claim 55 cannot be considered patentably distinct over claim 3 of the 6,365,410 patent when there is a specifically recited embodiment in claim 3 (the heterologous protein is an enzyme) that would anticipate claim 49 or claim 55. Specifically, the enzyme claimed in claim 49 and claim 55 is also claimed in claim 3 of the 6,365,410 patent. Additionally, claim 3 cannot be considered patentably distinct over claim 49 or claim 55 because it would have been obvious to one of ordinary skill to modify the method of claim 3 from patent 6,329,176 by also reciting that the microorganism to be cultured is also obtained to thus generate the instant invention. The ordinary skilled artisan would have

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been motivated to do this as the embodiment of also obtaining a microorganism is essential to the invention and the invention cannot be performed without also obtaining a microorganism. Given the teachings of the claims in 6,365,410 and the level of skill of the ordinary skilled artisan at the time of the invention, a reasonable expectation of success in practicing the claimed invention for evolved microorganism production would have been expected.

Additionally, if a patent resulting from the instant claims was issued and transferred to an assignee different from the assignee holding the 6,365,410 patent, then two different assignees would hold a patent to the claimed invention of 6,365,410, and thus improperly there would be possible harassment by multiple assignees.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The mutator gene cannot be selected from the group consisting of homologues of *mutD*, *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS*, *mutU* as these genes are wild-type genes (page 7, line 15-16) and according to the invention a mutator gene is a DNA repair gene with a mutation (page 4, line 29 – page 5, line 2). **This is a new rejection necessitated by applicant's amendment filed 4/18/03, paper No. 12.**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode, contemplated by the inventor of carrying out his invention.

Claim 53 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in Paper No. 11, mailed 1/13/03 and repeated below.**

The written description requirement for genus claims may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with known or disclosed correlations between function and structure, or by a combination of such characteristics sufficient to show that the applicant was in possession of the claimed genus. In the instant case, applicants only disclose *mutD* mutations but do not disclose homologues of *mutD* or mutations or homologues of any other *mut* genes. Given the absence of disclosed or art recognized correlations between structure and function of homologues and mutations of *mut* genes, the large number of potential mutations that can be generated in said genes and the uncertainty that any mutation or homologue will be functional, it must be considered that any mutation or homologue must be empirically determined. By disclosing *mutD* mutations, the applicants have not reduced to practice mutations and homologues of *mutT*, *mutY*, *mutM*, *mutH*, *mutL*, *mutS*, *mutU* genes. Given the diversity of the recited mutator genes, the absence of disclosed or art recognized structure-function relationships and the unpredictability of the art, the disclosure of one example

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in one genus would not represent to the skilled artisan a representative number of species sufficient to show applicants were in possession of claimed genus.

Response to Argument

It is acknowledged that applicant states that there is No Double Patenting but to expedite their business interests will submit a Terminal Disclaimer upon receiving notification that the Claims are allowed. The claims remain rejected until receipt of the Terminal Disclaimer.

Applicants traverse the claim rejections under 35 U.S.C 112, first paragraph, on page 11-12 of the amendment filed 4/10/03, Paper No. 12. Applicants argue that the claim is a method claim for preparing an evolved microorganism and includes the use of a mutator gene but is not directed toward the mutator gene. Applicant further argues that the choice of the specific mutator gene is irrelevant to the performance of the method.

Applicant's arguments filed 4/21/03 have been fully considered but they are not persuasive. By reciting mutator genes selected from the group consisting of mutator gene mutations and homologues of these genes, applicant recites a large and variant genus. Applicants have not clearly identified the genes that belong to this genus except by disclosing that a homologue refers to a functionally related DNA repair gene (page 7, line 16). Neither the prior art nor the specification has provided adequate written description to support or illustrate the genus encompassed by the claim. Without knowing what the genes are or what they look like, there is no description of the method as broadly claimed. Furthermore, the applicant must convey with reasonable clarity to those skilled in the art that they were in possession of the invention. While the claims are not drawn to the mutator gene but to a method of preparing an

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evolved microorganism, that method requires use of a mutator gene. Claim 52 recites that the microorganism comprises at least one copy of said mutator gene in its chromosome.

Conclusion

Claims 49, 53 and 55 are rejected.

Claims 50-52, 54 and 56-58 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B Marvich, PhD whose telephone number is (703) 605-1207. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucell, PhD can be reached on (703) 305-1998. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 305-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the patent analyst, Zeta Adams, whose telephone number is (703) 305-3553.

Maria B Marvich, PhD
Examiner
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TERRY MCKELVEY
PRIMARY EXAMINER